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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W., SUITE 600
WASHINGTON, DC 20005-3934

EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,679	PAUL ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *9,17-24,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-16,25-27 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-8, 10-16, 25-27 and 30, and SEQ ID NO:14, in Paper No. 12 is acknowledged. Applicant traverses a species election requirement on the ground(s) that all the nucleic acid species of Group I are closely related. This is not found persuasive because no requirement for an election of species was made in the office action mailed July 26, 2002. The office action explicitly stated that restriction to a single nucleic acid sequence and the amino acid sequence it encodes was also required under 35 USC 121 and 372. Applicant also traverses the requirement for restriction between the groups of inventions on the ground(s) that a common search of the groups would not be unduly burdensome, and on the ground(s) that all share a common feature in that they all comprise the sequences of Figure 1. This is not found persuasive because while the searches of Groups I-V may overlap, their searches are not coextensive of each other. In this particular instance, a search of Group I is not coextensive with a search of Groups II-V, since Group I requires a search for products not claimed in Groups II-III, and a search for methods not claimed in Groups IV-V. This is also not found persuasive because only claims 4-5 and 27 refer to Figure 1. Accordingly, claims 9, 17-24 and 28-29 and the nonelected sequences are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

Applicant's IDS form 1449, filed February 22, 2001, Paper No. 8, was not available for consideration at the time of the instant Office action.

Claim Objections

Claims 1-11, 13, 25 and 27 are objected to because of the following informalities: the appropriate article is missing before the word "nucleic acid". Appropriate correction is required.

Claims 4, 5 and 27 are objected to for failing to comply with the sequence rules. See 37 CFR 1.821(d). Appropriate correction is required.

Claim 27 is objected to for reciting sequences directed to nonelected inventions. Appropriate correction is required.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10-16 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any nucleic acid encoding a signal transduction protein involved in the process of dehiscence which is expressed in a dehiscence zone, to cells and plants comprising said nucleic acid, and to methods for obtaining said cells and plants. The claims are also broadly drawn to any nucleic acid encoding sequence variants of as low as 40% similarity, fragments therewith of any size or sequence, probes of any size and sequence, or nucleic acid molecules of any size or sequence which are uncharacterized other than the presence of a small primer.

The claims do not recite the specific identity of any particular signal transduction protein which the nucleic acid encodes. Absent reference to the particular identity of the signal transduction protein encoded by the nucleic acid molecule a critical element of the claimed invention remains undefined, such that the invention is not adequately described. In contrast, the specification describes a cDNA sequence of SEQ ID NO:14 isolated from *Brassica napus* that is expressed in the dehiscence zone of pods, and that encodes a putative protein having amino acid sequence homology to bacterial proteins of two-component regulatory systems (pages 21-25, Figures 1-4). The specification also describes a homolgous DNA sequence isolated from *Arabidopsis* (pages 27-28). The specification does not describe or characterize any additional nucleic acids that encode a signal transduction protein involved in the process of dehiscence.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter

sufficient to distinguish it from other materials." University of California v. Eli Lily and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, 12 and 16, and claims 14 and 15 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite in part c) for the omission of a transitional verb or phrase which indicates the relationship of this part to the protein in the preamble. Insertion of --is-- or --comprises-- after "c)", as intended, would obviate the rejection.

Claim 6 is indefinite in the recitation of "which is". It is unclear whether it is the nucleic acid as claimed in claim 1 "which is" dehiscence-zone expressed, or whether it is the one or more further nucleic acid "which is" dehiscence-zone expressed.

Claim 12 is indefinite in the recitation of "plant cell". There is insufficient antecedent basis for "plant cell" in claim 11, as only a cell is claimed in claim 11.

Claim 16 is indefinite in omission of essential method steps. Mere "growth" of a cell will result in callus production, not plant part or plant regeneration.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 10-12, 14-15, 25, 27 and 30 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-8, 10-12, 14-15, 25, 27 and 30, as written, do not sufficiently distinguish over nucleic acids, plants and cells as they exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the

inventor, e.g., by insertion of "Isolated" or "Purified" for nucleic acid claims, and by insertion of "transformed with" for plant cell or plant claims.

Claims 1-8, 10-16, 25-27 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to a nucleic acid encoding a signal transduction protein involved in the process of dehiscence which is expressed in a dehiscence zone, to cells and plants comprising said nucleic acid, and to methods for obtaining said cells and plants.

The specification discloses the isolation from *Brassica napus* of a DZ2 cDNA sequence of SEQ ID NO:14 that is expressed in the dehiscence zone of pods, and that encodes a putative protein having amino acid sequence homology to bacterial proteins of two-component regulatory systems (pages 21-25, Figures 1-4). Examples 4 and 5 of the specification also suggests that antisense downregulation of the DZ2 mRNA transcription may result in the production of shatter resistant *Brassica napus* plants, but the examples appear to be prophetic (pages 28-31). The specification also discloses the isolation from *Arabidopsis* of a DNA sequence that is homologous to SEQ ID NO:14 (pages 27-28). The specification does not disclose the structure or function of any additional nucleic acids that encode a signal transduction protein involved in the process of dehiscence.

First, the claimed invention lacks utility because no specific function has been demonstrated for the protein encoded by the claimed nucleic acid molecule. Although the specification reveals SEQ ID NO:14 encodes a protein having amino acid sequence homology to

bacterial proteins of two-component regulatory systems, no empirical data is provided to support a function for the protein encoded by SEQ ID NO:14. While empirical data is not required for patentability, the state of the art recognizes that while a functional assignment based on sequence comparisons may categorize a protein into a particular class of proteins or provide a starting point for verifying protein activity, it does not replace empirical data for confirming protein activity, as structural homology between amino acid sequences is not always predictive of their functional homology. For example, Doerks et al. teach that incorrect or incomplete sequence information within a database affects the predictive capacity of the database (Trends in Genetics, June 1998, Vol. 14, No. 6, pages 248-250, see page 248 column 1 paragraph 1). Doerks et al. also teach that query searches may identify shared homology with multiple groups of functionally unrelated proteins (Page 248 column 3 second full paragraph), that regions of shared homology may be nonfunctional regions (Page 248 column 3 third full paragraph), and that the degree of shared homology within a functional region does not always predict a conservation of the functional mechanism of that region (Page 248 column 3 fourth full paragraph).

Second, Applicant's claimed nucleic acid molecule lacks substantial utility under current utility guidelines. While the specification implies that the claimed isolated nucleic acid molecule is useful because it encodes a protein that functions as signal transduction protein involved in dehiscence, the specification does not disclose a signal transduction function for the protein encoded by SEQ ID NO:14, and the specification does not disclose the effect of expressing the claimed nucleic acid molecule in any plant, tissue or cell. Applicant does not teach how the claimed nucleic acid molecule or its encoded protein would be substantially beneficial to the public. Although isolated nucleic acid molecules encoding proteins of known function may have

a well established utility, isolated nucleic acid molecules encoding proteins of unknown function do not. It is apparent that extensive further research, not considered to be routine experimentation, would be required before one of skill in the art would know how to use the claimed invention. It has been established by the courts that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility.

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (Brenner v. Manson, 383 U.S. 519 (1966)).

Thus, while signal transduction activity associated with dehiscence has substantial benefit to the public, Applicant does not disclose that SEQ ID NO:14 encodes such a protein, and one skilled in the art cannot conclude that SEQ ID NO:14 encodes a protein with signal transduction function based upon Applicant's disclosure. Applicant's invention is not refined to the point where specific benefit exists in currently available form. As set forth above, one skilled in the art cannot readily take Applicant's claimed invention and derive immediate benefits from it based upon Applicant's disclosure. Accordingly, the claimed invention lacks a real world use. (see Utility Examination Guidelines published in the Federal Register, Vol. 66, No. 4, Friday, January 5, 2001, Notices, pages 1092-1099).

Claims 1-8, 10-16, 25-27 and 30 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a

well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-8, 10-15, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al. (1997, Plant Physiology, Vol. 114, pages 29-37, Applicant's search report).

The claims are drawn to a nucleic acid encoding a signal transduction protein involved in the process of dehiscence which is expressed in a dehiscence zone, to nucleic acids comprising promoters and/or additional dehiscence-expressed nucleic acids, to cells from any organism and plants comprising said nucleic acid, to methods for obtaining said cells, and to antisense nucleic acids.

Nelson et al. teach a nucleic acid encoding calreticulin (page 31 Table 1; page 32 Figure 1 and Tables II-III), and a signal transduction function for calreticulin (page 29 abstract and paragraph spanning columns 1 and 2). Nelson et al. also teach the involvement of calreticulin in the process of dehiscence (page 29 abstract; page 36 paragraph spanning columns 1 and 2). Additionally, Nelson et al. teach *E. coli* cells comprising said nucleic acid, and methods for obtaining said cells (page 30 column 2 last paragraph). Finally, teach *Arabidopsis* plants that

naturally comprise said nucleic acid operably linked to its promoter. The nucleic acid would inherently comprise a complementary strand which would be "antisense" to the sense strand. The *Arabidopsis* plants would naturally comprise other dehiscence-expressed nucleic acids.(page 35 Figure 6).

Remarks

No claim is allowed.

Claims 5, 16, 27 and 30 are deemed free of the prior art due to the failure of the prior art to teach or suggest an isolated nucleic acid molecule of SEQ ID NO:14, or plant cells or plants transformed therewith.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
January 13, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638